DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M2796n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

July 9, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. George Ajjan
President
The Women's Healthcare Group, P.C.
870 Palisade Avenue
Teaneck, New Jersey 07666

FILE NO.: 99-NWJ-30
Inspection ID NO.: 1549970005

Dear Mr. Ajjan:

Representatives from the Food and Drug Administration (FDA) and the State of New Jersey Radiation Control Program conducted an investigation at your facility on May 21, 1999. This investigation was in response to a complaint, which alleged that your mammography unit did not have any compression, and that your facility was not performing any Quality Control (QC) tests.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following findings at your facility as they relate to QC:

1. Processor QC charts were missing 13 out of 13 days of operation in May 1999. Processor charts were missing 100% for the processor in the darkroom at The Women's Healthcare Group.

2. Processor QC charts were missing 22 consecutive days for the processor in Room M35A at The Women's Healthcare Group.

3. Phantom QC records were missing for at least one month but less than three months for the mammography unit.

4. The compression device QC records were inadequate. The test had not been performed since October 18, 1998.

The above listed noncompliances have validated the claim that your facility was not performing the appropriate QC tests at the proper intervals. The specific problems noted above appear on your MQSA Facility Inspection Report (copy enclosed).

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the additional noncompliances that are listed on the enclosed inspection report. These noncompliances are:

5. The radiological technologist, [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.

6. The radiological technologist, [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.

Effectively immediately, [redacted] and [redacted] must stop performing independent mammography. They can only perform mammography under the direct supervision of a qualified technologist. Please note that direct supervision means that the qualified technologist must be physically present with [redacted] or [redacted] during the mammography procedure.

Additionally, the following noncompliance was observed:

7. The patient names are illegible on the mammography film, which could lead to reporting inaccurate results.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within five (5) working days from the date you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to: Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have questions about mammography facility requirements, or about the content of this letter, please fell free to contact Ms. Toniette Williams, MQSA Auditor at (973) 526-6018.

Sincerely,

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

Enclosure as Stated

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